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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,551	03/29/2004	Claudio Bucolo	P03491	3392

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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
06/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,551	BUCOLO ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-46* is/are pending in the application.

4a) Of the above claim(s) *15-22 and 29-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1pg(6/24/04), 1pg 9/14/05), 1pg11/03/06), 1pg(11/13/06)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-28, the species of hyaluronic acid as the viscoelastic polymer, hexahydric alcohol as the polyol, and hyaluronic acid as the polysaccharide, in the reply filed on 3/28/2008 is acknowledged.

Claims 15-22 and 29-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g. In re Wilder, *22 U*SPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did "little more than outline goals

appellants hope the claimed invention achieve and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "derivatives" used herein), however may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

A description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112, P 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have indicated what does not constitute the same. See, e.g.., In re Gostelli, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the claims are directed to a viscoelastic composition with various groups which may be polymerized. Among the list of instant claim 12 and 14 are "derivatives thereof." There is no relationship between the many possible derivatives and their function as a polymer.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the percentage of quenching" in line 1. There is insufficient antecedent basis for this limitation in the claim. Additionally, there is no

reference provided for calculating the percentage, i.e. percent by weight, mole, volume, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10-14, 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Escalon Ophthalmics Inc (WO 95/07085, see applicants IDS dated 11/13/06) in view of Stone (US 6,231,608).

Escalon Ophthalmics Inc teaches a viscoelastic aqueous composition (page 6 line1) which contains an active agent, hyaluronic acid (page 6 lines 1-6) where the concentration ranges from 1-5 g/ml (see fig 1), and a bufferant (pge 6 lines 7-10). The molecular mass is disclosed to cont be at least 50 kD (page 9 lines 20-23).

Escalon Ophthalmics Inc does not disclose the use of tris[hdroxymethyl]aminomethane as a bufferant.

Stone teaches trishydroxymethylaminomethane as a buffering agent for glycosidase compositions (column 11 lines 51-63).

Stone does not teach the addition of hyaluronic acid or a polyol.

One of ordinary skill in the art would look to other compositions to find a bufferant suggested by the primary which is suitable, such as disclosed in the secondary reference, resulting in the instantly claimed composition.

With regard to the viscosity, percentage of quenching, and shear-viscosities, where the compositions appear to contain the same amount of active ingredients and would have the same bufferant at the same pH, it would be expected that the composition essentially has these same properties.

Claims 1, 3-8, 10-14 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,671,903) in view of Stone (US 6,231,608).

Chen et al teaches a clear aqueous composition (claim 1) which contains an active agent, hyaluronic acid (claim 38) at less than 1% by weight (column 30 lines 1-9), a polyol, such as sorbitol or mannitol (claim 53), and a bufferant (claim 60).

Chen et al does not disclose the use of tris[hdroxymethyl]aminomethane as a bufferant.

Stone teaches trishydroxymethylaminomethane as a buffering agent for glycosidase compositions (column 11 lines 51-63).

Stone does not teach the addition of hyaluronic acid or a polyol.

One of ordinary skill in the art would look to other compositions to find a bufferant suggested by the primary which is suitable, such as disclosed in the secondary reference, resulting in the instantly claimed composition.

With regard to the viscosity, percentage of quenching, and shear-viscosities, where the compositions appear to contain the same amount of active ingredients and would have the same bufferant at the same pH, it would be expected that the composition essentially has these same properties.

Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,671,903) in view of Stone (US 6,231,608) and Gohzu et al (US 5,013,445).

Chen et al teaches a clear aqueous composition (claim 1) which contains an active agent, hyaluronic acid (claim 38) at less than 1% by weight (column 30 lines 1-9), a polyol, such as sorbitol or mannitol (claim 53), and a bufferant (claim 60).

Chen et al does not disclose the use of tris[hdroxymethyl]aminomethane as a bufferant or the amount.

Stone teaches trishydroxymethylaminomethane as a buffering agent for glycosidase compositions (column 11 lines 51-63).

Stone does not teach the addition of hyaluronic acid or a polyol.

Gohzu et al teaches the use of trishydroxymethylaminomethane in chemical compositions in an amount between 5-100 mM to achieve a pH of from 6.0 to 7.5 (claim 6).

One of ordinary skill in the art would look to other compositions to find a bufferant suggested by the primary which is suitable, such as disclosed in the secondary reference, resulting in the instantly claimed composition. Then to determine the amount, one of ordinary skill in the are would look to other uses of the bufferant, such as in Gohzu to determine the possible range.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,671,903) in view of Stone (US 6,231,608) and Wohlrab et al (US 6,689,349).

Chen et al teaches a clear aqueous composition (claim 1) which contains an active agent, hyaluronic acid (claim 38) at less than 1% by weight (column 30 lines 1-9), and a bufferant (claim 60).

Chen et al does not disclose the use of tris[hdroxymethyl]aminomethane as a bufferant or the molecular mass of the hyaluronic acid polymers.

Stone teaches trishydroxymethylaminomethane as a buffering agent for glycosidase compositions (column 11 lines 51-63).

Stone does not teach the addition of hyaluronic acid or the molecular mass of the hyaluronic acid.

Wohlrab et al discloses the mass of hyaluronic acid polymers in the range of 10-200 1500 kD and 1,000 and 4,500 kD (column 2 lines 39-48).

One of ordinary skill in the art would look to other compositions to find a bufferant suggested by the primary which is suitable, such as disclosed in the secondary reference, resulting in the instantly claimed composition. The mass of the polymer would then be recognized by looking to art that also uses hyaluronic acid as a polymer system.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Patent Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612